

Claim 40 is allowed.

Claims 38, 39, and 42 have been rejected.

By way of this amendment, claims 38, 39, and 42 are canceled without prejudice, claim 40 is amended, and new claims 54 – 101 are added.

Upon entry of this amendment claims 40 and 54 – 101 will be pending.

In view of the amendments presented herewith and the following remarks, Applicants respectfully request that the rejection of the claims be reconsidered and withdrawn.

Summary of the Amendment

Claim 40 is amended to clarify and more accurately describe that which is claimed. Support for the amendment can be found in the original claims and throughout the specification as originally filed (for example, at page 4, line 19, page 14, line 25, and page 15, lines 18 - 20). No new matter has been added.

New claims 54 – 101 are added for consistency and to refer to specific embodiments of the invention. Support for new claims 54 – 101 can be found in the original claims, and throughout the specification as originally filed (for example, page 2, lines 16 – 1, page 5, lines 31 – 38, page 7, lines 13 – 17 and 33 – 37, page 14, lines 8 – 11 and 21 – 30, and page 47, lines 24 - 30). No new matter has been added.

Supplemental Information Disclosure Statement

Applicants respectfully request a copy of the initialed Form PTO-1449 filed with the Supplemental Information Disclosure Statement on December 19, 2001

Allowed Claims

Applicants note with appreciation that claim 40 is allowed.

35 U.S.C. §112, second paragraph

Applicants note with appreciation that no rejection has been applied under 35 U.S.C. §112, second paragraph. Applicants would like to clarify the Office's understanding of the meaning of the phrases "substantially no toxicity" and "substantially reduced toxicity." Applicants stated previously (Response dated August 3, 2000) that these phrases would be understood by one of ordinary skill in the art to mean that the *H. pylori* cytotoxin (CT) polypeptides do not exhibit statistically significant cytotoxic effects, and would thus be acceptable for use in human vaccines.

Rejections under 35 U.S.C. §112, first paragraph

Claims 38, 39, and 42 have been rejected under 35 U.S.C. §112, first paragraph for alleged lack of enablement. Applicants respectfully traverse this rejection. Claims 38, 39, and 42 have been canceled without prejudice, rendering this rejection moot.

Claims 38, 39, and 42 have also been rejected under 35 U.S.C. §112, first paragraph as allegedly containing subject matter not described in the specification in such a way as to reasonably convey that the inventors had possession of the claimed invention at the time of filing of the application. Applicants respectfully traverse this rejection. Since claims 38, 39, and 42 have been canceled without prejudice, the rejection for this basis has also been rendered moot.

Applicants respectfully request that the rejection of claims 38, 39, and 42 under 35 U.S.C. §112, first paragraph be withdrawn.

Rejections under 35 U.S.C. §102

Claims 38, 39, and 42 have been rejected under 35 U.S.C. §102(b) as being allegedly anticipated by Joab *et al.*, 1987, J. Virol., 61:1140-1144, Murakami *et al.*, 1987, DNA, 6:189-197, Rettenmier *et al.*, 1986, J. Clin. Invest., 77:1740-1746, Trevino *et al.*, 1986, Infec. Immun., 53:129-134, Sibold *et al.*, 1984, Biochimie, 66:547-556, or Stunnenberg *et al.*, 1988,

DOCKET NO.: CHIR-0158 (0316.005)
PATENT APPLICATION

SERIAL NO.: 09/360,934
FILED: JULY 26, 1999

Nucleic Acids Res., 16:2431-2444. Applicants respectfully traverse this rejection. Claims 38, 39, and 42 have been canceled, rendering this rejection moot. Applicants respectfully request that the rejection of claims 38, 39, and 42 under 35 U.S.C. §102(b) be withdrawn.

Conclusion

Applicants respectfully submit that claims 40 and 54 – 101 are in condition for allowance. A notice of allowance is earnestly solicited. If the Examiner feels a telephonic interview would be helpful, she is asked to call the undersigned at 215-557-5901.

Attached hereto is a marked-up version of claim 40 showing the changes made thereto by the current amendment. The attached page is captioned “**Version with markings to show changes made.**”

Respectfully submitted,



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the claims:

40 (Thrice Amended). A recombinant [recombinantly produced *H. pylori* CT] polypeptide comprising at least ten contiguous amino acids from SEQ ID NO:3 [or a fragment thereof], which polypeptide [or fragment thereof]:

- (i) [comprises at least ten amino acids of SEQ ID NO:3,
- (ii)] can induce the production of antibodies to *Helicobacter pylori* cytotoxin (CT) polypeptide [*H. pylori*,] and
- (ii) [(iii)] exhibits substantially no toxicity, or substantially reduced toxicity.

Claims 38, 39, and 42 are canceled without prejudice.

New claims 54 – 101 are added.